

10/681,416

- 2 -

**Amendments to the Claims:**

Please cancel Claim 22. Please amend Claims 1 and 20.

The Claim Listing below will replace all prior versions of the claims in the application:

**Claim Listing:**

1. (Currently Amended) A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system of a subject, in a single, breath-activated step, comprising:  
administering particles comprising a bioactive agent, from a receptacle having a mass consisting of said particles, to a subject's respiratory tract, wherein:
  - i) the particles administered to the subject's respiratory tract have a tap density of less than  $0.4 \text{ g/cm}^3$ ;
  - ii) at least 50% of the particles have a fine particle fraction less than  $4.0 \text{ }\mu\text{m}$ ; and
  - iii) at least about 50% of the mass of particles stored in the receptacle is delivered to the pulmonary system of the subject.
2. (Original) The method of Claim 1 wherein the particles have a tap density of less than about  $0.1 \text{ g/cm}^3$ .
3. (Original) The method of Claim 1 wherein the particles have a geometric diameter greater than about  $5 \text{ }\mu\text{m}$ .
4. (Original) The method of Claim 1 wherein the receptacle has a volume of at least about  $0.37 \text{ cm}^3$ .
5. (Original) The method of Claim 1 wherein the receptacle has a volume of at least about  $0.48 \text{ cm}^3$ .

10/681,416

- 3 -

6. (Original) The method of Claim 1 wherein the receptacle has a volume of at least about 0.67 cm<sup>3</sup>.
7. (Original) The method of Claim 1 wherein the receptacle has a volume of at least about 0.95 cm<sup>3</sup>.
8. (Original) The method of Claim 1 wherein delivery is primarily to the deep lung.
9. (Original) The method of Claim 1 wherein delivery is primarily to the central airways.
10. (Original) The method of Claim 1 wherein the bioactive agent is albuterol sulfate.
11. (Original) The method of Claim 1 wherein the bioactive agent is insulin.
12. (Original) The method of Claim 1 wherein the bioactive agent is growth hormone.
13. (Original) The method of Claim 1 wherein the bioactive agent is fluticasone.
14. (Original) The method of claim 1 wherein the bioactive agent is salmeterol.
15. (Original) The method of Claim 1 wherein the bioactive agent is a hydrophobic drug.
16. (Original) The method of Claim 1 wherein the bioactive agent is a hydrophilic drug.
17. (Original) The method of Claim 1 wherein the bioactive agent is a monoclonal antibody.
18. (Original) The method of Claim 1 wherein the particles are in the form of a dry powder.

10/681,416

- 4 -

19. (Original) The method of Claim 1 wherein administration to the respiratory tract is by a dry powder inhaler.
20. (Currently Amended) A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system of a subject, in a single breath, comprising:  
administering dry powder particles comprising a bioactive agent, from a receptacle having a mass consisting of said particles, to a subject's respiratory tract in a single breath,  
wherein:
  - i) the particles have a tap density less than about  $0.4 \text{ g/cm}^3$ ;
  - ii) at least about 5 milligrams of the bioactive agent is delivered to the pulmonary system of the subject.
21. (Original) The method of Claim 1 wherein said particles are spray dried particles.
22. Canceled.
23. (Original) The method of Claim 1 wherein at least 75% of the particles have a fine particle fraction less than  $6.8 \text{ }\mu\text{m}$ .
24. (Original) The method of Claim 20 wherein at least 50% of the particles have a fine particle fraction less than  $4.0 \text{ }\mu\text{m}$ .
25. (Original) The method of Claim 20 wherein at least 75% of the particles have a fine particle fraction less than  $6.8 \text{ }\mu\text{m}$ .
26. (Original) The method of Claim 20 wherein said particles are spray dried particles.
27. (Original) The method of Claim 20 wherein the particles deliver at least 10 milligrams of the bioactive agent.